25 April 216
EMA/PDCO/244355/2016
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 27-29 April 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

27 April 2016, 08:30- 19:00, room 3A

28 April 2016, 08:30- 19:00, room 3A

29 April 2016, 08:30- 13:00, room 3A

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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1. Introductions

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 27-29 April 2016. See PDCO April 2016 minutes (to be published post May 2016 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 27-29 April 2016.

1.3. Adoption of the minutes

PDCO minutes for 30 March-1 April 2016.

2. Opinions

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

2.1. Opinions on Products

2.1.1. EMEA-001841-PIP01-15

Type 2 Diabetes Mellitus

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.2. Recombinant humanized anti-MMP9 monoclonal antibody IgG4 - EMEA-001813-PIP01-15

Crohn's Disease, Ulcerative Colitis

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.3. EMEA-001809-PIP01-15

Treatment of bacterial infections caused by Gram-negative bacteria

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.4. EMEA-001832-PIP01-15

Treatment of Chronic Hepatitis C / Treatment of Chronic Hepatitis C

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.5. pimavanserin - EMEA-001688-PIP02-15

Treatment of schizophrenia and other psychotic disorders

Day 120 opinion

Action: For adoption

Psychiatry

2.1.6. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) - EMEA-001715-PIP01-14

Influenza / Prevention of influenza

Day 120 opinion

Action: For adoption

Vaccines

2.1.7. Rosuvastatin (Calcium) / Olmesartan medoxomil - EMEA-001914-PIP01-15

Hypertension, Dyslipidaemia, Cardiovascular events / Treatment of dyslipidaemia/hypercholesterolaemia, Prevention of cardiovascular events, Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.8. Imetelstat Sodium - Orphan - EMEA-001910-PIP01-15

Janssen-Cilag International N.V; Treatment of Myelofibrosis

Day 60 opinion

Action: For adoption

Oncology

2.1.9. Ciclosporin - EMEA-001916-PIP01-15

Keratoconjunctivitis sicca

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.10. D-stereoisomer of c-Jun N-terminal Kinase Inhibitor 1 - Orphan - EMEA-001926-PIP01-16

Auris Medical Ltd.; ASNHL comprising idiopathic sudden sensorineural hearing loss (ISSNHL; also called sudden deafness), acute acoustic trauma (AAT), and surgery induced acoustic trauma

Day 60 opinion

Action: For adoption; Oral explanation meeting to be held on Wednesday 27 April 2016, 14:00-15:00 UK time

Oto-rhino-laryngology

2.1.11. Tramadol hydrochloride / Ibuprofen arginine - EMEA-001887-PIP01-15

Acute pain

Day 60 opinion

Action: For adoption

Pain

2.1.12. Peanut flour - EMEA-001753-PIP02-15 - early adoption of opinion

Treatment of peanut allergy

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.2. Opinions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

2.2.1. Sirukumab - EMEA-C2-001043-PIP01-10-M02

Janssen-Cilag International N.V.; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.2.2. maraviroc - EMEA-C-000020-PIP01-07-M05

ViiV Healthcare UK Limited; Treatment of human immunodeficiency virus (HIV-1) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.2.3. Dasatinib - EMEA-C3-000567-PIP01-09-M04

Bristol-Myers Squibb Pharma EEIG; Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia

Day 60 opinion

Action: For adoption

Oncology

2.2.4. Riociguat - EMEA-C3-000718-PIP01-09-M05

Bayer Pharma AG; Treatment of pulmonary hypertension

Opinion adopted via written procedure on 18 April 2016

Action: For information

Cardiovascular Diseases

2.2.5. Tobramycin - EMEA-C-000184-PIP02-14 – early adoption of opinion

Novartis Europharm Limited; Treatment of P. aeruginosa pulmonary infection/colonisation in patients with cystic fibrosis

Day 30 opinion

Action: For adoption

Infectious Diseases

2.2.6. midostaurin - EMEA-C2-000780-PIP01-09-M02 – early adoption of opinion

Novartis Europharm Limited; Treatment of acute myeloid leukaemia

Day 30 opinion

Action: For adoption

Oncology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. dihydroartemisinin / piperaquine tetraphosphate - EMEA-000153-PIP01-07-M03

Sigma-Tau SpA; Uncomplicated malaria caused by Plasmodium falciparum (ICD-10 code B50) / Treatment of uncomplicated malaria caused by Plasmodium falciparum

Day 60 opinion

Action: For adoption

2.3.2. Liraglutide - EMEA-000128-PIP02-09-M02

Novo Nordisk A/S; E66 Obesity / Treatment of obesity

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.3. retosiban - EMEA-001359-PIP01-12-M03

GlaxoSmithKline Trading Services Limited; Treatment of spontaneous preterm labour / Treatment of spontaneous preterm labour to improve neonatal outcomes by prolonging pregnancy in women with an uncomplicated singleton pregnancy between 24 and less than 34 weeks gestation

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. Tolvaptan - EMEA-001231-PIP02-13-M03

Otsuka Pharmaceutical Europe Ltd.; Polycystic Kidney Disease (PKD), Dilutional hyponatraemia / Treatment of chronic (>48 hours) dilutional hyponatraemia resistant to fluid

restriction (i.e., euvolemic and hypervolemic hyponatremia) associated with heart failure, cirrhosis or SIADH, Treatment of progression of ADPKD, Treatment of progression of ARPKD

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.5. potassium sulphate / magnesium sulphate heptahydrate / sodium sulphate anhydrous - EMEA-000816-PIP02-10-M01

IPSEN Pharma; Diagnostic of organic and/or functional bowel diseases / In adults and children from 6 months of age for bowel cleansing prior to any procedure requiring a clean bowel (e.g. bowel visualisation including endoscopy and radiology or surgical procedure). The product is not a treatment for constipation.

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.6. efmorocotocog alfa - EMEA-001114-PIP01-10-M03

Biogen Idec Ltd; Hereditary Factor VIII Deficiency - D66 / Treatment and prophylaxis of bleeding in patients with severe Haemophilia A (congenital FVIII deficiency)

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.7. Secukinumab - EMEA-000380-PIP02-09-M03

Novartis Europharm Limited; Chronic Idiopathic Arthritis / Treatment of juvenile psoriatic arthritis, Treatment of enthesitis-related arthritis JIA

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.8. raltegravir - EMEA-000279-PIP01-08-M05

Merck Sharp & Dohme (Europe), Inc.; Human Immunodeficiency Virus (HIV-1) infection / In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.9. Alemtuzumab - EMEA-001072-PIP01-10-M02

Genzyme Europe B.V.; Multiple sclerosis / For paediatric patients with relapsing remitting multiple sclerosis (RRMS) with active disease on prior disease modifying treatment (DMT) defined by clinical or imaging features.

Day 60 opinion

Action: For adoption

Neurology

2.3.10. Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins - EMEA-001039-PIP02-12-M02

Merz Pharmaceuticals GmbH; Treatment of sialorrhea / Treatment of chronic troublesome sialorrhea associated with neurological conditions (e.g. cerebral palsy, traumatic brain injury) and/or intellectual disability in children and adolescents aged 2 – 17 years.

Day 60 opinion

Action: For adoption

Neurology

2.3.11. Melatonin - Orphan - EMEA-000440-PIP02-11-M04

RAD Neurim Pharmaceuticals EEC Ltd; Insomnia - children, Insomnia - adults, Insomnia

Day 60 opinion

Action: For adoption

Neurology

2.3.12. ibrutinib - Orphan - EMEA-001397-PIP03-14-M01

Janssen-Cilag International N.V.; Treatment of mature B-cell neoplasm / Treatment of children from 1 year to less than 18 years of age with newly-diagnosed and relapsed/refractory mature B-cell lymphoma, that is, diffuse large B-cell lymphoma or Burkitt and Burkitt-like lymphoma.

Day 60 opinion

Action: For adoption

Oncology

2.3.13. darbepoetin alfa - EMEA-000329-PIP02-09-M05

Amgen Europe B.V.; Drug-induced aplastic anaemia, Treatment of anaemia due to chronic

disorders / Treatment of symptomatic anaemia in adult and paediatric cancer patients with non-myeloid malignancies receiving chemotherapy, Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adults and paediatric patients

Day 60 opinion

Action: For adoption

Oncology / Uro-nephrology

2.3.14. tafluprost - EMEA-001187-PIP01-11-M03

Santen Oy; Glaucoma (ICD: H40) / Tafluprost preservative-free is indicated for the treatment of elevated intraocular pressure in paediatric patients 1 month post-natal to less than 18 years of age

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.15. Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins - EMEA-001039-PIP01-10-M02

Merz Pharmaceuticals GmbH; Treatment of muscle spasticity, Treatment of dystonia, Treatment of muscle induced wrinkles / , Treatment of spasticity of the upper and/or lower limb in children and adolescents (aged 2 - 17 years) with cerebral palsy

Day 60 opinion

Action: For adoption

Ophthalmology / Dermatology / Neurology

2.3.16. Atrasentan hydrochloride - EMEA-001666-PIP01-14-M01

AbbVie, Ltd; Nephropathies / Treatment of multidrug-resistant nephrotic syndrome (MDR-NS)

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.17. Ferric citrate coordination complex - EMEA-001213-PIP02-12-M02

Keryx Biopharma UK Ltd.; Treatment of hyperphosphataemia / The control of hyperphosphataemia in patients with chronic kidney disease (CKD)

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.18. Eltrombopag (eltrombopag olamine) - EMEA-000170-PIP01-07-M04 – early adoption of opinion

Novartis Europharm Limited; Treatment of Idiopathic Thrombocytopenia Purpura (ITP) / Treatment of Chronic Idiopathic thrombocytopenic purpura (ITP)

Day 30 opinion

Action: For adoption

Haematology-Hemostaseology

2.4. Opinions on Re-examinations

2.4.1. Coagulation Factor VIIa (Recombinant) - EMEA-001203-PIP02-14-M01

LFB SA; Treatment of congenital coagulation disorders, Treatment of acquired haemophilia / Treatment of bleeding and prevention of bleeding in those undergoing surgery or invasive procedures in patients with haemophilia A or B with inhibitors to Factors VIII or IX, Treatment of bleeding and prevention of bleeding in those undergoing surgery or invasive procedures in patients with acquired haemophilia

Opinion on re-examination

Action: For adoption

Haematology-Hemostaseology

2.5. Finalisation and adoption of opinions

3. Discussion of applications

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

3.1. Discussions on Products D90-D60-D30

3.1.1. Eleclazine - EMEA-001697-PIP01-14

Treatment of congenital long QT syndromes / Indicated for the treatment of long QT syndrome type 2 (LQT2), Indicated for the treatment of long QT syndrome type 3 (LQT3)

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.2. Eleclazine - EMEA-001697-PIP02-14

Treatment of hypertrophic cardiomyopathy / Indicated for the treatment of symptomatic hypertrophic cardiomyopathy (HCM)

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.3. Metreleptin - Orphan - EMEA-001701-PIP01-14

Aegerion Pharmaceuticals Ltd; Treatment of lipodystrophy

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. Humanized monoclonal modified immunoglobulin G4 (IgG4) antibody with bispecific structure targeting factors IX, IXa, X and Xa - Orphan - EMEA-001839-PIP01-15

Roche Registration Limited; Treatment of Hereditary FVIII Deficiency / Indicated for the routine prophylaxis to reduce the frequency of or prevent bleeding episodes in paediatric patients with hemophilia A with FVIII inhibitors

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. Cadazolid - EMEA-001108-PIP02-15

Enterocolitis due to Clostridium difficile / Treatment of Clostridium difficile-associated diarrhea (CDAD)

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.6. cytarabine 100 mg (liposome combination) daunorubicin HCl 44mg (liposome combination) - Orphan - EMEA-001858-PIP01-15

Celator (UK) Ltd; Acute myeloid leukemia / treatment of acute myeloid leukemia

Day 90 discussion

Action: For discussion

Oncology

3.1.7. Glycopyrronium bromide (dose expressed as free base) / Mometasone furoate / Indacaterol acetate (dose expressed as free base) - EMEA-001812-PIP01-15

Treatment of asthma

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.8. A phosphorothioate oligonucleotide targeted to apolipoprotein C-III - Orphan - EMEA-001915-PIP01-15

Ionis Pharmaceuticals; Familial Chylomicronemia Syndrome

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.9. efpeglenatide - EMEA-001903-PIP01-15

Type 2 diabetes mellitus

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.10. Antithrombin alfa - EMEA-001154-PIP02-15

Treatment of congenital antithrombin deficiency, Treatment of acquired antithrombin deficiency (Preeclampsia), Treatment of acquired antithrombin deficiency (ECMO) / Prophylaxis of peri-partum thromboembolic events in congenital antithrombin deficient patients., Antithrombin supplementation during ECMO procedure, Treatment of pregnant women less than 30 weeks GA with preeclampsia to prolong gestation and decrease foetal and neonatal morbidity and mortality.

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.11. abatacept - EMEA-000118-PIP03-15

Treatment of childhood-onset SLE / Treatment of childhood-onset lupus nephritis caused by childhood-onset SLE with abatacept in combination with MMF or CY, and CS in pediatric patients 5 years of age and older who have had an insufficient response to MMF or CY, and CS.

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.12. Ciprofloxacin Hydrochloride - EMEA-001563-PIP02-15

Treatment of cystic fibrosis related bronchiectasis associated with P. aeruginosa infection, Treatment of non-cystic fibrosis related bronchiectasis associated with P. aeruginosa infection (NCFBEPA+)

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.13. synthetic surfactant protein B analogue / synthetic surfactant protein C analogue / 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoglycerol sodium salt / dipalmitoylphosphatidylcholine - Orphan - EMEA-001780-PIP01-15

Chiesi Farmaceutici SpA; treatment of respiratory distress syndrome (RDS) / treatment of respiratory distress syndrome (RDS) in preterm neonates of less than 37 weeks of gestational age

Day 60 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.14. benzodiazepine - EMEA-001918-PIP01-15

Treatment of autism spectrum disorder

Day 60 discussion

Action: For discussion

Neurology

3.1.15. N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid - EMEA-001930-PIP01-16

Prevention of Meningococcal Disease

Day 60 discussion

Action: For discussion

Vaccines

3.1.16. alvimopan - EMEA-001922-PIP01-15

Postoperative ileus

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.17. Ascorbic Acid / Sodium Ascorbate / Potassium Chloride / Sodium Chloride / Sodium Sulfate / Macrogol 3350 - EMEA-001705-PIP02-15

Diagnosis of large intestine disorders / For bowel cleansing prior to any clinical procedures requiring a clean bowel e.g. bowel endoscopy or radiology

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.18. Susoctocog alfa - EMEA-000753-PIP02-16

Congenital haemophilia A with antibodies (inhibitors) to human factor VIII / Peri-operative management in patients with congenital haemophilia A with antibodies (inhibitors) to human FVIII, On-demand treatment and control of bleeding episodes in patients with congenital haemophilia A with antibodies (inhibitors) to human FVIII

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.19. Fc- and CDR-modified humanized monoclonal antibody against C5 - EMEA-001943-PIP01-16

Atypical Haemolytic Uremic Syndrome / Treatment of atypical Haemolytic Uremic Syndrome

Day 30 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

3.2. Discussions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

3.2.1. Expanded Human Allogeneic Mesenchymal Adult Stem Cells Extracted from Adipose Tissue - EMEA-C1-001561-PIP01-13

TiGenix S.A.U.; Treatment of anal fistula

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.2.2. Ciclosporin - EMEA-C-000575-PIP01-09-M03

SANTEN OY; Treatment of vernal keratoconjunctivitis

Day 30 discussion

Action: For discussion

Ophthalmology

3.2.3. cinacalcet - EMEA-C-000078-PIP01-07-M07

Amgen Europe B.V.; Treatment of secondary hyperparathyroidism in patients with end-stage renal disease

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Landiolol hydrochloride - EMEA-001150-PIP02-13-M01

AOP Orphan Pharmaceuticals AG; Treatment of supraventricular arrhythmias / Treatment of sinus tachycardia or supraventricular tachyarrhythmias, including junctional ectopic tachycardia (JET), atrial flutter (AF), atrial fibrillation (AFL), focal atrial tachycardia (FAT), atrioventricular re-entrant tachycardia (AVRT), and atrioventricular nodal re- entrant tachycardia (AVNRT), peri-operatively (during an induction phase, intra-operatively, and during the weaning phase), or when in the phycisian's judgement control of the heart rate is required.

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. rCFP-10 (recombinant 10 kD culture filtrate protein) / rdESAT-6 (recombinant dimer of 6 kD early secretory antigenic target) - EMEA-001156-PIP01-11-M07

Statens Serum Institut; Diagnosis of tuberculosis / To diagnose individuals suspected to be infected with Mycobacterium tuberculosis from 28 days of age

Day 30 discussion

Action: For discussion

Diagnostic

3.3.3. Canagliflozin - EMEA-001030-PIP01-10-M06

Janssen-Cilag International NV; Renal Disease in Patients with Type 2 Diabetes Mellitus, Type 2 Diabetes Mellitus / Treatment of Type 2 Diabetes Mellitus, Treatment of Renal Disease in Patients with Type 2 Diabetes

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. corifollitropin alfa - EMEA-000306-PIP01-08-M03

Merck Sharp & Dohme Limited; Inability to achieve pregnancy, female / hypogonadotropic hypogonadism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. dulaglutide - EMEA-000783-PIP01-09-M04

Eli Lilly & Company; Type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Liraglutide - EMEA-000128-PIP01-07-M07

Novo Nordisk A/S; E11 Non-insulin-dependent diabetes mellitus / Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Naloxegol (as naloxegol oxalate) - EMEA-001146-PIP01-11-M02

AstraZeneca AB; Treatment of opioid induced constipation

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.8. caplacizumab (anti-von Willebrand Factor Nanobody) - Orphan - EMEA-001157-PIP01-11-M01

Ablynx NV; Treatment of thrombotic thrombocytopenic purpura / Treatment of acquired thrombotic thrombocytopenic purpura

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.9. Deferasirox - Orphan - EMEA-001103-PIP01-10-M03

Novartis Europharm Limited; Treatment of chronic overload requiring chelation therapy / Treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in patients with others anemias, Treatment of chronic transfusional iron overload in patients with beta thalassemia major, Treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.10. Eltrombopag - EMEA-000170-PIP03-13-M01

Novartis Europharm Limited; Bone Marrow Depression and Hypoplastic Anaemia / Treatment of cytopenias in paediatric patients with severe aplastic anaemia who are no receiving hematopoietic stem cell transplant

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.11. baricitinib - EMEA-001220-PIP01-11-M01

Eli Lilly & Company Limited; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis) / Treatment of juvenile idiopathic arthritis, Treatment of JIA-associated uveitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.12. belimumab - EMEA-000520-PIP01-08-M05

Glaxo Group Limited; Systemic lupus erythematosus / Treatment of systemic lupus erythematosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.13. Eculizumab - Orphan - EMEA-000876-PIP05-15-M01

Alexion Europe SAS; Myasthenia Gravis / Treatment of Refractory Generalized Myasthenia Gravis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.14. letermovir - Orphan - EMEA-001631-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Prevention of cytomegalovirus infection / Prevention of CMV viremia and/or disease in at-risk patients having undergone an allogeneic HSCT or SOT

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. EMEA-001411-PIP01-12-M03

Gilead Sciences International Ltd; Chronic Viral Hepatitis C infection / Chronic Viral Hepatitis C infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.16. Brivaracetam - Orphan - EMEA-000332-PIP01-08-M10

UCB Pharma SA; Treatment of epilepsy with partial onset seizures, Treatment of neonatal seizures / Treatment of neonatal seizures with adjunctive administration of brivaracetam, Treatment of paediatric patients with partial onset seizures

Day 30 discussion

Action: For discussion

Neurology

3.3.17. Decitabine - Orphan - EMEA-000555-PIP01-09-M05

Janssen-Cilag International NV; Acute Myeloid Leukaemia / Treatment of paediatric patients with acute myeloid leukaemia who have high-risk cytogenetics, or are refractory to, or have a relapse after first line treatment

Day 30 discussion

Action: For discussion

Oncology

3.3.18. Regorafenib - EMEA-001178-PIP01-11-M02

Bayer Pharma; Treatment of all conditions contained in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) / Treatment of paediatric patients with a solid malignant tumour(s) integrated with anti-cancer therapy

Day 30 discussion

Action: For discussion

Oncology

3.3.19. Methoxyflurane - EMEA-000334-PIP01-08-M04

Medical Developments UK Ltd; treatment of acute pain

Day 30 discussion

Action: For discussion

Pain

3.3.20. 1-(2,2-difluoro-1,3-benzodioxol-5-yl)-N-{1-[(2R)-2,3-dihydroxypropyl]-6-fluoro-2-(1-hydroxy-2-methylpropan-2-yl)-1H-indol-5-yl}cyclopropanecarboxamide / Ivacaftor - Orphan - EMEA-001640-PIP01-14-M01

Vertex Pharamceuticals (Europe) Ltd; Cystic Fibrosis / Treatment of Cystic Fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.21. AGOMELATINE - EMEA-001181-PIP01-11-M03

Les Laboratoires Servier; Major Depressive Episodes / Major Depressive Episodes

Day 30 discussion

Action: For discussion

Psychiatry

4. Nominations

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

4.1. List of letters of intent received for submission of applications with start of procedure 21 June 2016 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

4.2. Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.

Action: For adoption

4.3. Nominations for other activities

Action: For adoption

5. Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6. Discussion on the applicability of class waivers

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6.1. Discussions on the applicability of class waiver for products

6.1.1. Seribantumab - EMEA-11-2016

Treatment of breast carcinoma/ In combination with exemestane or fulvestrant for the treatment of postmenopausal women and men with ER positive, HER2 negative, HRG positive advanced breast cancer following prior cyclin-dependent kinase inhibitor therapy for advanced or metastatic disease

Action: For adoption

6.1.2. EMEA-12-2016

Androgen receptor modulators for treatment of prostate malignant neoplasms/ Treatment of patients with high risk non-metastatic castration-resistant prostate cancer (nmCRPC) as defined by a prostate specific antigen (PSA) doubling time of ⩽ 10 months

Action: For adoption

6.1.3. Rovalpituzumab tesirine - EMEA-13-2016

Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ Treatment of adult patients with DLL3-expressing extensive stage small cell lung cancer which have received at least two prior systemic therapies, including a platinum-based regimen; or as maintenance therapy in patients who have achieved clinical benefit from front-line platinum-based chemotherapy

Action: For adoption

6.1.4. Chimeric monoclonal antibody against claudin-18 splice variant 2 - EMEA-14-2016

Treatment of gastric adenocarcinoma/ Treatment of adult patients with advanced metastatic CLDN18.2-positive, HER2-negative adenocarcinoma of the stomach and gastroesophageal junction (including Siewert type I, II, III tumors) on top of on top of platinum and fluoropyrimidine-based standard of care chemotherapy

Action: For adoption

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

7.1. Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver

None

8. Annual reports on deferrals

Note: The annual reports on deferrals to be noted by the members of the PDCO are flagged in the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

None

9.2. Coordination with EMA Scientific Committees or CMDh-v

9.2.1. Committee for Medicinal Products for Human Use (CHMP)

Action: For information

9.2.2. Draft Agenda for the Strategic Review and Learning Meeting to be held on 1-3 June 2016 in Utrecht, the Netherlands

PDCO member: Hendrik van den Berg, Maaike van Dartel

Action: For discussion

9.2.3. Canagliflozin – INVOKANA (CAP); canagliflozin, metformin – VOKANAMET (CAP)

Applicant: Janssen-Cilag International N.V; Treatment of type 2 diabetes mellitus

PRAC Rapporteur: Valerie Strassmann

Scope: Article 20 procedure to PRAC was triggered by European Commission on 15 April 2016, Signal of potential increased risk of lower limb amputations

Action: For information

9.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Jacqueline Carleer

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Inventory of paediatric therapeutic needs – respiratory

PDCO member: Ninna Gullberg, Sabine Scherer

Action: For adoption

9.4. Cooperation within the EU regulatory network

9.4.1. Reflection on the late submission of PIPs

PDCO Chair: Dirk Mentzer

Action: For information

9.4.2. EU Network Training Centre (EU NTC) Paediatric Curriculum

Action: For discussion

9.4.3. 10-year Report to the European Commission (EC)

Action: For discussion

9.5. Cooperation with International Regulators

None

9.6. Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee

None

9.7. PDCO work plan

None

9.8. Planning and reporting

None

9.9. PDCO ORGAM

9.9.1. PDCO ORGAM Draft Minutes for 16 March 2016

Action: For adoption

9.10. Other

9.10.1. EMA Workshop on the use of Single Arm Trials in Oncology products to be held on 30 June 2016

Action: For information

10. Any other business

10.1. None

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 18:00 - 19:00, room 3M

11.1.2. Neonatology

Action: For discussion on Thursday, 18:00 - 19:00, room 3L

11.1.3. Inventory

Action: For discussion on Thursday, 18:00 - 19:00, room 3K

12. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Paediatric investigation plan (PIP) (section 2.1 Opinion on PIPs and section 3.1 Discussions on PIPs)
A paediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of a medicine for children. Pharmaceutical companies submit proposals for PIPs to the European Medicines Agency's Paediatric Committee (PDCO). This Committee is responsible for agreeing or refusing the plan.

Compliance checks (section 2.2 Opinions on Compliance check, section 3.2 Discussions on Compliance check)
A compliance check may be necessary before any application for marketing authorisation (even for an adult indication) can be considered valid, if there was no deferral for at least one of the studies agreed in the PIP, or after the due date of initiation or completion of a study/measure. The same applies to some regulatory applications for authorised products, as described above.

Modification of an Agreed Paediatric Investigation Plan (section 2.3 Opinions on Modification of an agreed PIP, section 3.3 Discussions on Modification of an agreed PIP)
The development plan for a medicine can be modified at a later stage as knowledge increases.
Modifications can also be made if the applicant encounters such difficulties with the implementation of a PIP, which render it unworkable or no longer appropriate.
In some cases, studies can be deferred until after the studies in adults have been conducted. This ensures that research in children is done only when it is safe and ethical to do so. Even when studies are deferred, the PIP will include details of the paediatric studies and their timelines.

Class waiver (section 6 Discussion on the applicability of class waiver)
As some diseases do not affect children (for example Parkinson's disease), the development of medicines for these diseases should not be performed in children. In these cases, a PIP is not required and it will be waived**.** For more information on the classes of diseases subject to waivers,
see class waivers.

Annual reports on deferrals (section 8)
If the medicinal product is approved in the EU, annual reports on the deferred measures in the PIP must be submitted to the Agency.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/